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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,681	06/27/2003	David Wynn	MCP-5016 NP	8293

27777 7590 04/03/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,681	WYNN ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

The Applicants' Amendments and Remarks filed 19 January 2007, in response to the Official Action mailed 16 October 2006, have been received.

Claim Objections

The objection to Claims 9 and 16 is hereby withdrawn by the examiner in light of the aforementioned Applicants' Amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. The rejection of Claims 14-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn by the examiner in view of the specification, page 3, lines 26-30, wherein a definition for "substantially free of" is detailed.

2. The rejection of Claims 1-5 and 7-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn by the examiner in view of

the aforementioned Applicants' Remarks, page 7, and the specification, page 11, lines 6-12.

3. Claims 1-5, 7-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2 and 14 recite a weight average molecular weight without providing units for the molecular weight. It is unclear if the molecular weight is measured in grams/mole, Daltons, etc. Claims 3-5, 7-13 and 15-17 are dependent from and include all the limitations of Claims 1 or 14, and are likewise indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-5 and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,835,187 (hereinafter Reuter et al.) in view of Lachman et al. (The Theory and Practice of Industrial Pharmacy, 1986) and U.S. Patent No. 5,637,313 (hereinafter Chau et al.).

Applicant claims:

The Applicant claims an IR dosage form comprising a plurality of particles containing ibuprofen having a particle size of about 150 μm to about 400 μm; and a matrix comprising hydroxypropylmethylcellulose with an average molecular weight of about 60,000 to about 5,000,000 and/or a viscosity of from about 3,000 mPa·s to about 150,000 mPa·s.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Reuter et al. teach an immediate release composition in chewable solid dosage form comprising: a plurality of inert silica particles of about 10 millimicrons (i.e., 10 nm or 0.01 μm) comprising ibuprofen, which is present in an amount of from about 40 wt.% to about 70 wt.%; USP hydroxypropylmethylcellulose grades E, F and K (e.g., Methocel/HPMC E4MP) having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa·s to about 5,600 mPa·s) and present in an amount ranging from 15 wt.% to about 50 wt.%; and mannitol (abstract; column 1, lines 1-68; column 2, lines 1-68; column 3, lines 6-68; column 4, lines 6, 22 and 56-68; column 5, lines 1-9). Reuter et al. further teach incorporating the taste neutral ibuprofen

powder in pharmaceutical dosage forms for oral administration (column 1, lines 45-61; and Claims1-9).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Reuter et al. do not teach the composition comprising a matrix comprising the hydroxypropylmethylcellulose. However, Chau et al. teach the formation of a soft, chewable, tablet dosage form wherein the components, such as hydroxypropylmethylcellulose, are contained in a matrix, and the active ingredient, such as ibuprofen, may be incorporated in the matrix during mixing or thereafter (column 3, lines 10-48 and 65-66; column 4, lines 3 and 4; and column 5, line 29). Chau et al. further teach that their dosage form lends itself to easy manufacture, good taste masking, improved texture, and easy manipulation of bioavailability (column 3, lines 37-41). Chau et al. further teach their dosage form is particularly well suited to the incorporation of encapsulated active ingredients (column 3, lines 42-43).

Also, Reuter et al. do not explicitly teach the instantly claimed particle diameters ranging from about 150 µm to about 400 µm. However, Lachman et al. teach to systematically adjust the diameters of said particles during the course of routine experimentation so as to obtain a free-flowing composition exhibiting desired flow properties that are suitable for manufacturing processing (page 315, column 2, lines 6-24; page 316, column 2, lines 51-58; page 316, column 1, lines 1-23). Lachman et al. further teach that particles having particle diameters of less than or equal to 150 µm result in a composition exhibiting undesirable flow properties, such as clumping, and

thus undesirable manufacturing processing characteristics, as reasonably suggested by Lachman et al. (page 315, column 2, lines 6-24; page 316, column 2, lines 51-58; page 316, column 1, lines 1-23).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to make a soft, chewable tablet with a plurality of particles containing ibuprofen and hydroxypropylmethylcellulose, as taught by Reuter et al., wherein the hydroxypropylmethylcellulose is incorporated into a matrix for the purpose of easy manufacture, good taste masking, improved texture, and easy manipulation of bioavailability as taught by Chau et al, and the particle sizes are adjusted so as to obtain a free-flowing composition exhibiting desired flow properties that are suitable for manufacturing processing, as reasonably suggested by Lachman et al. A skilled artisan would have reasonably expected similar results since Reuter et al. suggests the incorporation of the ibuprofen particles in a dosage form and Chau et al. teaches incorporating hydroxypropylmethylcellulose into a matrix for the purpose of easy manufacture, good taste masking, improved texture, and easy manipulation of bioavailability.

While Reuter et al. do not explicitly teach the instantly claimed particle diameters ranging from about 150 µm to about 400 µm, it is well within the purview of the skilled artesian to determine the optimal diameter of said particles by systematically adjusting the diameters thereof during the course of routine experimentation. One of ordinary skill

in the art at the time the instant application was filed would have been motivated to systematically adjust the diameters of said particles during the course of routine experimentation so as to obtain a free-flowing composition exhibiting desired flow properties that are suitable for manufacturing processing, as reasonably suggested by Lachman et al.

Also, one of ordinary skill in the art at the time the instant application was filed would have been motivated to increase the particle diameters of Reuter et al. so as to avoid excessive van der Waals attractive forces that exist among particles having particle diameters of less than or equal to 150 μm, which result in a composition exhibiting undesirable flow properties, such as clumping, and thus undesirable manufacturing processing characteristics, as reasonably suggested by Lachman et al. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 7-17 have been considered but are moot in view of the new grounds of rejection as discussed herein above.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nathan W. Schlientz, Ph.D.
Patent Examiner
Technology Center 1600
Group Art Unit 1616

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616